P1/5

510(K) SUMMARY

MAR 11 2003

Subject 510(k) Number K023564

Sponsor

Osseus, LLC

1118 South Orange Avenue; Suite 203
Orlando, Florida 32806

Official Contact

Shawn T. Huxel, President/GM
34 Woodlane Road
Lawrenceville, New Jersey 08648
Phone - (908) 997-0127
Fax - (908) 842-0347
Mobile - (908) 896-5893

Proprietary Name

Osse-Lign

Common Name

Metallic Internal Fixation Device

Classification Name and Reference

888.3010 - Bone Fixation Cerclage

Regulatory Class

Class II

Device Product Code

(Panel 87) JDQ

Date Prepared

22 October, 2002

Brief Description of Device

There is a need for an orthopaedic implant system that combines the minimally invasive techniques possible with traditional tension band wires with the strength, tensioning and security of modern cable systems.

Current tension cable devices currently in use achieve the re-approximation and compression of fractured bones by a cerclage method. The cable or wire is wrapped around the outside of the bone, implants and/or grafts. A crimp or swage fitting is then attached to the cable in such a way that both ends of the cable pass through the crimp or swage in opposite directions. Thus, a circle of cable is formed with the cable sliding freely through the crimp or swage. The circle or loop of cable is then tightened around the bone with one of a variety of tensioning tools. The tension is increased until the bony fragments are appropriately compressed together. A second tool is then used to crimp or swage the cable in order to prevent the cable from sliding, thereby securing the cable in tension, subsequently compressing the bone. A third tool is then used to cut the excess cable material.

Existing cerclage systems have numerous drawbacks. The cerclage method requires that the cable encircles the bone. As a result, an open surgical approach with extensive dissection of soft tissues must be performed. The cerclage method also requires large tools capable of tensioning the cable in two directions 180 degrees apart and crimping the cable with large devices. This increases the need for a large incision. Often, in order to securely grip the crimp for tensioning, tension in the cable must sometimes be released, resulting in loss of compression at the fracture site. Furthermore, by encircling the bone completely, periosteal blood flow is restricted in the area near the cable, potentially inhibiting fracture healing. Finally, many fracture types could benefit from the application of strong, flexible fixation with cables, but are not prone to the application of a cerclage method.

The Osse-Lign system incorporates cables that are similar in form and material to existing cable systems. However, the Osse-Lign system incorporates a unique set of tools, cable attachments and surgical approaches that permit the surgeon to achieve fracture compression and fixation either without completely encircling the bone or with a minimally invasive cerclage technique. Insertion of the Osse-Lign cables through minimally invasive surgical approaches is made possible by the unique implants and instrumentation. Finally, the in line cable fixation capability permits the use of cables through, rather than around fractures thereby increasing the possible indications for cables in fracture fixation.

Implants

The Osse-Lign system comprises implants and instruments designed to permit the insertion, tensioning, crimping and cutting of cables without the need for cerclage or large incisions. The outer diameter of the cable is 2 millimeters (2mm). The cable and all

implants are manufactured from certified medical implant grade 316LVM (Low Carbon, Vacuum Melt) Stainless Steel. 316LVM Stainless Steel is currently used in a number of orthopedic and general surgical implants. The cable is of a 7X7X7 configuration.

Cables have fittings mechanically swaged or crimped onto the ends of the cable in the factory setting using power-crimping tools. No welding, adhesives, coatings or other materials are required in these processes thereby eliminating the risk of corrosion or introduction of impurities into the metal during the assembly process.

Instruments

The Osse-Lign System instrumentation consists of the following reusable manual orthopedic instruments:

- Crimping Tool
- Cutting Tool
- Tensioning Tool
- Flip Anchor Insertion Tool/Cable Passer

Indications for Use

The Osse-Lign System is indicated for general orthopedic repairs. This includes such procedures as long bone fractures, bone grafting and reinforcement of bone. This system may also be used for supplementary fixation and reduction with approved bone plates, screws, pins, nails and bone grafting material.

Long Bone Fractures

- Femur fractures
- Tibia fractures
- Humerus fractures

Joint Fractures

- Ankle fractures
- Knee Fractures
- Hip Fractures
- Shoulder Fractures
- Elbow Fractures

Other bone fractures

- Olecranon
- Pelvis fractures
- Patella fractures
- Acetabular fractures
- Trocanteric reattachment
- Fixation of fractures in conjunction with I/M nailing and plating techniques
- Stabilization of cortical onlay strut graft
- Temporary reduction techniques for ORIF (Open Reduction Internal Fixation)

K023564 p5/5

Basis for Substantial Equivalence

The substantial equivalence of the Osse-Lign System is based on the equivalence in intended use, materials, operational principals, and indications and contraindications to:

- BMP™ Cable System by Biomet (K982545)
- Dall-Miles™ Cerclage System by Howmedica (K971741, K961569)
- SDB Cerclage System by Pioneer Laboratories (K992616)
- Stainless Steel Cerclage Wire manufactured prior to 1976

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 11 2003

Mr. Shawn T. Huxel
President/GM
Osseus, LLC
34 Woodlane Road
Lawrenceville, New Jersey 08648

Re: K023564
Trade/Device Name: Osse-Lign Internal Fracture Fixation System
Regulatory Number: 21, CFR 888.3010
Regulation Name: Bone fixation cerclage
Regulatory Class: II
Product Code: JDQ
Dated: February 24, 2003
Received: February 25, 2003

Dear Mr. Huxel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Milhern

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510 (K) NUMBER IF KNOWN: K023564

DEVICE NAME: Osse-Lign Internal Fracture Fixation System

The Osse-Lign System is indicated for general orthopedic repairs. This includes such procedures as long bone fractures, bone grafting and reinforcement of bone. This system may also be used for supplementary fixation and reduction with approved bone plates, screws, pins, nails and bone grafting material.

Long Bone Fractures

- Femur fractures
- Tibia fractures
- Humerus fractures

Joint Fractures

- Ankle fractures
- Knee Fractures
- Hip Fractures
- Shoulder Fractures
- Elbow Fractures

Other bone fractures

- Olecranon
- Pelvis fractures
- Patella fractures
- Acetabular fractures
- Trocanteric reattachment
- Fixation of fractures in conjunction with I/M nailing and plating techniques
- Stabilization of cortical onlay strut graft
- Temporary reduction techniques for ORIF (Open Reduction Internal Fixation)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE, IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ **or** **Over-the-Counter Use** _____

(Per 21 CFR 801.109) (Optional Format 1-2-1996)

for Mark N Milhern

(Division Sign-Off)

Division of General, Restorative and Neurological Devices

510(k) Number K023564